How E-connected medicine will change the value of pharmaceuticals

Overview of current initiatives on digital pill

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Agenda

• Burden of non compliance

• Overview of the potential advantages of current digital pills initiative from various perspectives
  – Patient
  – Caregiver
  – Doctor
  – Provider

• Effectiveness and efficiency and consideration in HTA evaluation
Burden of non compliance

• Recent study estimated that the annual adjusted disease-specific economic cost of non-adherence per person ranged from $949 to $44,190 (in 2015 US$)\(^1\)

Simple initiative often not sufficient

• A very large randomized clinical trial (53,480 enrollees of a pharmacy benefit manager) did not show a statistically significant difference in adherence was found between those in the control group and those who received a reminder device (pill bottle strip with toggles, digital timer cap, or standard pillbox)\(^1\)

\(^1\)Choudhry NK. Effect of Reminder Devices on Medication Adherence: The REMIND Randomized Clinical Trial. JAMA Intern Med. 2017 May 1;177(5):624-631.
Current initiatives

- **Severe Mental Illness**
  - In 2017 U.S. regulators approved the first medicine with an embedded sensor to help keep track of whether patients with mental illness are adhering to their prescriptions.

- **Hepatitis C**
  - Denver Health is conducting study using digital pill to track adherence and compliance of Hepatitis, a viral disease that impacts the liver and can be fatal but is also curable through often expensive medicines.

- **Opioids**
  - Denver Health is conducting study using digital pill to track adherence and compliance

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Severe Mental Illness

- **Principle of Digital medicine system (DMS) **

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1 Neuropsychiatric Disease and Treatment 2018:14 553–565
Benefits (1/2)

• The pill will allow doctors to track better than ever how well people stick to a course of medication.
  – Understand the reason for poor efficacy
• Will support the caregiver in helping patient monitoring treatment intake and decrease anxiety of caregiver on patient’s compliance
  – Dialogue on adherence and reassurance
• May also discover vital new information about treating hepatitis C or SMIR and respond to the question on “how often you need to take your hepatitis C or SMI medication to be cured” ¹
  – Inför; development strategy and new vision of adherence


Benefits (2/2)

• For opioid determining adherence to a prescribed medication regimen and measuring the ways in which patients ingest as-needed medications pose methodological challenges with usual methods
  – patients determine opioid ingestion dose and frequency based on temporal perception of pain
  – thus common measures of adherence (eg, smart pill bottles, pharmacy refill histories, or patient diaries) are impractical or provide aggregate measures that cannot delineate temporal patterns of opioid ingestion¹.
• Precise measures of opioid ingestion patterns are important because they can suggest incomplete treatment of pain, the development of tolerance, or the transition into problematic use ²

¹ Chai et al. Med Internet Res. 2017 Jan 13;19(1)Digital Pills to Measure Opioid Ingestion Patterns in Emergency Department Patients With Acute Fracture Pain: A Pilot Study.
Concern

• DMS can be seen as a form of surveillance and may be experienced as intrusive, coercive, or an invasion of privacy by people who experience mental illness\(^1\)
• There are legitimate reasons people may be mindfully nonadherent to prescribed medication regimens, such as psychological resistance to treatment, wishes to avoid undesirable side effects burdensome medication costs, a lack of trust in providers’ advice, and treatment goals that may conflict with those of their providers— including attempts to decrease medication use.
• Behavioral psychology acceptability
• Absent strict legal orders, people have the right to manage their medications without oversight or covert pressure.

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Discussion

• Digital pill is a promising new tool that
  – Should be mandatory in clinical trials
  – could benefit patients, caregiver and doctors
  – Open a new field of the most important clinical pharmacology topic
  – Enhance value for payer and society
• Will allow researchers to understand better the use of medications in a unprecedented way that could influence the development of new drugs
• However ethical concerns must be consider so this tool does not become a coercive tool

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